510(K) SUMMARY

Given® Diagnostic System

510(k) Number K022980

FEB 2 7 2003

Applicant's Name:

Given Imaging Ltd.
P.O. Box 258, New Industrial Zone
Yokneam 20692, Israel
Tel.: 011-972-4-9097730
Fax: 011-972-4-9592466;

Contact Person:

Shoshana Friedman, RAC
V.P. Regulatory & Medical Affairs
Tel: 011-972-4- 9097784
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Email: shosh@givenimaging.com

Trade Name:

Given® Diagnostic System

Classification Name:

Ingestible Telemetric Gastrointestinal Capsule Imaging System

Classification:

FDA has classified Ingestible Telemetric Gastrointestinal Capsule Imaging System as class II devices (product code 78NZE) and they are reviewed by the Gastroenterology Panel.

Predicate Device:

- Given® Diagnostic Imaging System (K010312)
- Given® Diagnostic System (K020341)
- Given® Diagnostic System (K022362)

Performance Standards and Special Controls:

The Given® Diagnostic System complies with the requirements presented in "Class II Special Controls Guidance Document;

Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA" issued on November 28,2001

Intended Use:

The Given® Diagnostic System is intended for visualization of the small bowel mucosa. It may be used as an adjunctive tool in the detection of abnormalities of the small bowel.

The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas.

Device Description:

The Given® Diagnostic System is comprised of three subsystems: M2A™ Capsule, Data Recorder Set, and RAPID® Workstation.

The M2A® Capsule is a wireless, disposable capsule designed to glide smoothly through the digestive system by the peristaltic activity of the intestinal muscles and is excreted naturally. During its passage, the capsule transmits digital data that is captured by receiving antennas attached to the patient's body. The images are stored in the DataRecorder that is connected to the receiving antennas and is worn on a belt around the waist of the patient. When the test is over, the antennas and recorder are removed from the patient's body. The images from the recorder are downloaded to the RAPID® Workstation for processing and viewing by the physician.

The RAPID 2.0 software, the subject of this submission, contains an optional feature called Suspected Blood Indicator (SBI), which automatically marks images that correlate with the existence of suspected blood or red areas. The analysis is based on detection of colorimetric abnormalities, or deviations from an expected spectrum, corresponding to normal tissue.

Substantial Equivalence:

The proposed modified Given® Diagnostic System is substantially equivalent to the Given® Diagnostic System cleared under K010312, K020341, and K022362. The verification activities demonstrated that the proposed modification does not raise any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2003

Shoshana (Shosh) Friedman, RAC
V. P. Regulatory & Medical Affairs
Given Imaging Limited
New Industrial Park
P.O. Box 258, Yoqneam
20692 ISRAEL

Re: K022980
Trade/Device Name: Given® Diagnostic System (Suspected Blood Indicator (SBI))
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: 78 NEZ
Dated: November 27, 2002
Received: December 3, 2002

Dear Ms. Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K022980

Device Name:

Given® Diagnostic System

Indications for Use:

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510(k) Number K022980

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022980